

Point of Care tests for HCV in community settings

No Point of Care (PoC) tests for HCV are currently entered on the ARTG and approved for use in Australia. However, a number of anti-HCV tests which show a similar specificity and sensitivity to commercial laboratory anti-HCV enzyme immunoassays have Federal Drug Administration (FDA) approval and European Union CE marking. These or similar tests may be approved for entry on the ARTG in the future if the sponsors of the tests make application to the TGA and the tests meet the Australian regulatory requirements.

In general, PoC tests do not have the sensitivity and specificity or negative and positive predictive values of laboratory-use only tests. The latter tests must reach high standards of quality assurance where the testing is performed by skilled operators in an environment appropriate for potentially infectious samples. Issues relevant to the use of PoC tests in Australia include the lack of regulatory oversight and quality assurance of the performance of the assays, the inability to regulate appropriate infection control at the place of testing, and the availability at the testing site of trained personnel for obtaining consent and delivering results. These tests are likely to be inappropriate for testing of low prevalence populations. Despite these drawbacks, there has been rapid improvement in the quality of PoC tests, new technologies are being investigated and the range and demand for such tests is expanding.

Should one or more of these PoC tests be approved for entry on the ARTG, they would find a niche in HCV testing in Australia as they offer an opportunity for testing of people who may otherwise not seek help from traditional medical settings and can provide a result without the individual returning to the site at a later date.

Studies are recommended to define optimal use of PoC tests, particularly in settings where HCV prevalence is low (resulting in low predictive values).

When a PoC test is approved for use in Australia, this section of the policy will be updated.